not include new mater and request that the amendments be entered. Applicants will be discussing the amendments to the claims in their remarks below.

I. RESPONSE TO REJECTION UNDER 35 U.S.C. U.S.C. §102(E)

On page 2 of the Action the Examiner rejected claims 1-3, 7-10 and 17-21 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 6,284,764 ("the '764 patent").[1] The Examiner refers applicants to examples 75, 76, 125 and 141 of the '764 patent. Applicants have hereinabove amended claim 1 of the subject application by incorporating the limitation of claim 4 providing for specific definitions of the R^3 substituent. Applicants respectfully submit that amended claim 1 is novel over the '764 patent and furthermore that the Examiner of the subject application has implicitly acknowledged the novelty of claim, i.e., claim 4 was considered to be novel by the Examiner in the December 31, 2002 Office Action. Applicants have hereinabove-cancelled claims 2, 3 and 17 to 20 thus rendering the novelty rejection of the aforementioned claims moot. With respect to rejected claims 7 to 10 and 21 they each depend directly on amended claim 1, thus these claims are novel over the '764 patent. Applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. §102(e) rejection.

II. RESPONSE TO REJECTION UNDER 35 U.S.C. U.S.C. §103(A)

On pages 2 and 3 of the Action the Examiner rejected claims 4, 5 and 11 under 35 U.S.C. §103(a) as allegedly obvious over 6,284,764 ("the '764 patent"). The Examiner refers applicants to the previous rejection and states that claim 4 corresponds to t = 0 whereas the prior art allegedly has t = 1. The Examiner further states that the '764 patent discloses that R^3 can be R^8 and R^8 can be aryl (phenyl) substituted by R^{10} (citing column 59, lines 34-35). The Examiner then states "[f]or a choice of R10, see column 59, line 59 and note that if t =0, this is the Heterocycle-(CR1R2)q-O- substituent seen here. Note that q can be 0-5 as seen at page 59, lines 62-63. Thus, the reference teaches the equivalence exactly." The Examiner further notes that the first two choices in claim 6 are thus obvious.

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[1] Applicants note that the Examiner included claim 20 in the rejection. Claim 20 is part of the subject matter of the non-elected group II restricted by the Examiner. Claims elected for examination were claims 1-19 and 21 (Group I). Applicants have also herein cancelled the non-elected claim 20 from the present application.

With respect to claim 11 the Examiner states that it has k =1 (rather than k = 0 of the prior art compunds) presents a similar issue, except that it arises with R^4 not R^3. The Examiner further states that the reference at column 2, lines 62-63 teaches that k = 0 to 5 so that any number in that range is an obvious variation.

For claim 5 the Examiner states that it presents an additional issue, the 3-isomer, whereas the prior art compounds are the 2-pyridyl. The Examiner states that it is well established that position isomers are *prima facie* structurally obvious even in the absence of a teaching to modify. The Examiner states that the isomer is expected to be preparable by the same method and to have generally the same properties. The Examiner states that this is deemed the motivation for preparing the position isomers. The Examiner further states that this has occurred many times in the past (citations omitted). The Examiner concludes this rejection by noting that the heterocycle can be bound in any position (citing column 11, lines 53-55) not just the 2-position of the examples.

Applicants respectfully traverse the Examiner's rejection of claims 4, 5, 6 and 11 under 35 U.S.C. §103(a) as obvious over the '764 patent and respectfully request the Examiner reconsider in view of the following remarks.

A *prima facie* case of obviousness requires the satisfaction of three criteria: (i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the references when combined must teach or suggest all of the claim limitations. *See* M.P.E.P. § 2143. Applicants respectfully submit that the Examiner has failed to establish each and every element of a *prima facie* obviousness rejection for claims 4, 5, 6 and 11 of the subject application.

Initially, applicants' note that the Examiner has failed to point to *any* teaching or suggestion in the '764 patent of the subject matter claimed in the present application. The Examiner merely recites bits and pieces from the '764 patent using applicants' disclosure as the blue print to arrive at the claimed invention. This is of course improper. The Examiner has failed to step into the shoes of those of ordinary skill in the art at the time of applicants' claimed invention. Rather the Examiner has improperly stepped into applicants' shoes by using the information disclosed in the present application to arrive at the claimed invention. The Examiner has provided *no* rhyme or reason to arrive at the claimed invention.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so in either the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 21 USPQ2d 1941 (Fed. Cir. 1992). Where is the motivation or suggestion in the '764 patent to modify it to arrive at the claimed invention? The Examiner certainly has not shown applicants where such a motivation or suggestion exists. Applicants respectfully submit that there is no motivation or suggestion in the '764 patent which would lead one of ordinary skill in the relevant art to modify its teachings to arrive at the claimed invention. What is the rationale or logic to picking the substituents the Examiner has focused on? None is provided in the Action.

For example, the Examiner's rejection of claim 4 of the present application relies upon a significant number of assumptions and unsupported intellectual modifications to arrive at the claimed invention based upon the teachings of the '764 patent. The initiation point for the Examiner's arrival at the claimed invention is to refer applicants to the 102(e) rejection and state that claim 4 corresponds to t = 0 while the prior art compounds have t = 1. Applicants respectfully request the Examiner to support his point of commencement for this rejection. Where does the '764 patent teach or suggest that the precise point of modification of the compounds of the '764 patent is employing compounds wherein t is 0 and not 1. Where did the Examiner derive that particular idea? Applicants, as stated above, respectfully submit that it is based merely on the disclosure of the present invention, which is *not* part of the prior art. From the hundredths of modifications one could make in the art why did the Examiner choose this particular modification. What in the art taught or suggested that this was the appropriate modification?

The next unsupported modification is the selection of R^8 from the art as an aryl and more particularly as a "phenyl" substituted by a very particular R^{10} substituent identified by the Examiner as heterocycle-(CR^1R^2)q-O. Applicants' respectfully submit that R^{10} provides for the following list of substituents shown below:

> each R^{10} is independently selected from halo, cyano, nitro, trifluoromethoxy, trifluoromethyl, azido, hydroxy, C_1-C_6 alkoxy, C_1-C_{10} alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, $-C(O)R^6$, $-C(O)OR^6$, $-OC(O)R^6$, $-NR^6C(O)R^7$,

$-NR^6C(O)NR^1R^7$, $-NR^6C(O)OR^7$, $-C(O)NR^6R^7$, $-NR^6R^7$, $-NR^6OR^7$, $-SO_2NR^6R^7$, $-S(O)_j(C_1\text{-}C_6$ alkyl) wherein j is an integer from 0 to 2, $-(CR^1R^2)_t(C_6\text{-}C_{10}$ aryl), $-(CR^1R^2)_t$(4-10 membered heterocyclic), $-(CR^1R^2)_qC(O)(CR^1R^2)_t(C_6\text{-}C_{10}$ aryl), $-(CR^1R^2)_qC(O)(CR^1R^2)_t$(4-10 membered heterocyclic), $-(CR^1R^2)_tO(CR^1R^2)_q(C_6\text{-}C_{10}$ aryl), **$-(CR^1R^2)_tO(CR^1R^2)_q$(4-10 membered heterocyclic)**, $-(CR^1R^2)_qS(O)_j(CR^1R^2)_t(C_6\text{-}C_{10}$ aryl), and $-(CR^1R^2)_qS(O)_j(CR^1R^2)_t$(4-10 membered heterocyclic), wherein j is 0, 1 or 2, q and t are each independently an integer from 0 to 5, 1 or 2 ring carbon atoms of the heterocyclic moieties of the foregoing R^{10} groups are optionally substituted with an oxo (=O) moiety, and the alkyl, alkenyl, alkynyl, aryl and heterocyclic moieties of the foregoing R^{10} groups are optionally substituted with 1 to 3 substituents independently selected from halo, cyano, nitro, trifluoromethyl, trifluoromethoxy, azido, $-OR^6$, $-C(O)R^6$, $-C(O)OR^6$, $-OC(O)R^6$, $-NR^6C(O)R^7$, $-C(O)NR^6R^7$, $-NR^6R^7$, $-NR^6OR^7$, $C_1\text{-}C_6$ alkyl, $C_2\text{-}C_6$ alkenyl, $C_2\text{-}C_6$ alkynyl, $-(CR^1R^2)_t(C_6\text{-}C_{10}$ aryl), and $-(CR^1R^2)_t$(4-10 membered heterocyclic), wherein t is an integer from 0 to 5; (bold emphasis added)

Applicants have bolded the R10 substituent chosen apparently by the Examiner in the absence of the present applicants' disclosure. Applicants' respectfully request the Examiner detail the teaching or suggestion in the '764 patent to arrive at the selection of this particular substituent. The Examiner appears to be only matching up pieces of applicants' claimed invention to elements found in the art without any rhyme or reason for their selection. The Examiner may not employ hindsight by using the applicant's disclosure as a blueprint to reconstruct the claimed invention out of isolated teachings in the prior art. Nor may the Examiner focus on the obviousness of the differences between the claimed invention and the prior art rather than on the obviousness of the claimed invention as a whole as § 103 requires. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 93 (Fed. Cir. 1986). Obviousness cannot be established by hindsight combination to produce the claimed

invention or in view of the teachings or suggestions of the inventor. *In re Dance*, 48 U.S.P.Q.2d 1635 (Fed. Cir. 1998); *In re Gorman*, 18 U.S.P.Q.2d 1885, 1888 (Fed. Cir. 1991). It is the prior art itself, and not the applicant's achievement, that must establish the obviousness of the combination. *In re Dance*, 48 U.S.P.Q.2d 1635 (Fed. Cir. 1998); *Interconnect Planning Corp. v. Feil*, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985).

The Examiner stated on page 3 of the Action that the first two choices in claim 6 are ". . . thus obvious, as these raise exactly the same issue." (referring to the Examiner's rejection of claim 4). Applicants respectfully submit that the rejection of claim 6 is without foundation and basis for the same reasons as setforth above for the rejection of claim 4.

Although every element of a claimed invention may be found in the prior art, this alone is not sufficient to negate patentability. *In re Rouffet*, 47 U.S.P.Q.2d 1453 (Fed. Cir. 1998). To prevent the use of hindsight based on the invention to defeat patentability of the invention, the examiner is required to show a motivation to combine or modify the references that create the case of obviousness. *In re Rouffet*, 47 U.S.P.Q.2d 1453 (Fed. Cir. 1998); *In re Jones*, 21 U.S.P.Q.2d 1941, 1943 (Fed. Cir. 1992); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 227 U.S.P.Q. 657, 664 (Fed. Cir. 1985). In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. *In re Rouffet*, 47 U.S.P.Q.2d 1453 (Fed. Cir. 1998). The Examiner has not met the standard for an obviousness rejection based upon the well-established rules of law. No where has the Examiner provided a motivation to modify the teachings of the '764 patent to arrive at the claimed invention. That teaching is only found in applicants disclosure not in the '764 patent. Why would one of ordinary skill in the art select the substituents so readily identified by the Examiner? The Examiner is required to conduct his obviousness evaluation *in the absence* of applicants' disclosure *not* use it as the road map to arrive at the desired invention.

With respect to claim 11 the Examiner again is engaged in the impermissible practice of hindsight construction to arrive at the claimed invention not based on the teachings of the '764 patent but on the teachings of applicants' own disclosure. The Examiner asserts that the claim 11 presents a similar issue as claim 4 by the selection of k equal to 1 rather than k equal to 0 for prior art compounds. The Examiner makes this significant leap to column 2, lines 62-63 for the disclosure in the '764 patent that t is 0 to 5 and concludes that "any number in that range is an obvious variation". Applicants, again, point out that the Examiner has

provided no underlying support or rationale for applicants selection of R^4 as a particular substituent wherein k is 1 to 3 (not just k is 0). Once again the Examiner is engaged impermissible hindsight to arrive at the claimed invention based upon applicants' disclosure. This is improper and not permitted. The Examiner has to find the teaching or suggestion to arrive at the claimed invention in the prior art not in applicants' disclosure.

The Examiner rejected claim 5 on the premise of positional isomers (3-isomer versus 2-isomer). Applicants' note that the Examiner did not identified any particular compound in this rejection to exemplify his position that applicants were claiming positional isomers. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs, analogs, or isomers, either geometric isomers (cis v. trans) or position isomers (e.g., ortho v. para), because they often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties. In all of these cases, however, the prior art teaches a specific, structurally-definable compound and the question becomes whether the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention. *In re Jones*, 21 U.S.P.Q.2d 1941, 1944 (Fed. Cir. 1992); *In re Grabiak*, 226 U.S.P.Q. 870, 872 (Fed. Cir. 1985)("In the case before us there must be adequate support in the prior art for the [prior art] ester/[claimed] thioester change in structure, in order to complete the PTO's prima facie case and shift the burden of going forward to the applicant."); *In re Lalu*, 223 U.S.P.Q. 1257, 1258 (Fed. Cir. 1984) ("The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound."); *In re Stemniski*, 170 U.S.P.Q. 343, 347 (C.C.P.A. 1971); *In re Taborsky*, 183 U.S.P.Q. 50, 55 (C.C.P.A. 1974); *In re Murch*, 175 U.S.P.Q. 89 (C.C.P.A. 1972); *In re Fay*, 146 U.S.P.Q. 47 (C.C.P.A. 1965).

Once again the Examiner has made significant assumptions to arrive at the compounds of claim 5. No where does the Examiner provide the rationale or logic to make the present invention. Nor does the Examiner provide any reasons to make the particular molecular modifications necessary to achieve the claimed invention. That information is found in applicants' disclosure not the prior art. However, the Examiner is once again constructing the claimed invention by picking particular discrete elements of the art to arrive at the claimed invention. No explanation of how the art teaches or suggest that one of ordinary skill in the art would make the present compounds based upon the disclosure of the

'764 patent is provided. In short, applicants direct the Examiner's attention to the excerpted definition of R^{10} above from the '764 patent which provides for a large range of subsituents. In the Examiner's remarks concerning claim 5 on page 4 of the Action the Examiner recites the bolded selection of "heterocycle-(CR1R2)q-" as supportive of the rejection. Applicants note that the random selection of elements of a claimed invention is not sufficient to render it obvious, more is required. The Examiner has not provided that here.

Furthermore, the Examiner has not identified any teaching or suggestion in the '764 patent to make any particular modification let alone make the highly specific selection of 3-isomers. That teaching is found in applicants' disclosure not the prior art. The Examiner is using an "obvious to try" standard and not the legally correct standard under U.S. practice of obviousness. "Obvious to try" has long been held not to constitute obviousness. *In re O'Farrell*, 7 U.S.P.Q.2d 1673, 1680-81 (Fed. Cir. 1988); *In re Geiger*, 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987); *In re Goodwin*, 198 U.S.P.Q. 1, 3 (C.C.P.A. 1978); *In re Antonie*, 195 U.S.P.Q. 5, 8 (C.C.P.A. 1977); *In re Lindell*, 155 U.S.P.Q. 521, 523 (C.C.P.A. 1967); *In re Tomlinson*, 150 U.S.P.Q. 623 (C.C.P.A. 1966); *In re Papesch*, 137 U.S.P.Q. 43 (C.C.P.A. 1963).

Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claim 4, 5, 6 and 11 under U.S.C. §103(a) as allegedly obvious over the 764 patent. If the Examiner maintains his rejection of the claims of the subject application, applicants respectfully request that the Examiner inform applicants with precision where the motivation or suggestion exists in the art to arrive at the claimed invention in the absence of the specification of the present application.

III. REJECTION UNDER THE JUDICIALLY CREATED DOCTRINE OF OBVIOUS-TYPE DOUBLE PATENTING

On page 4 of the Office Action claims 1-5, 7-11 and 17-21 of the subject application stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-20 of the '764 patent. The Examiner further states that the alleged conflicting claims are not identical, they are not patentably distinct from each other for the reasons provided above in the section 103 rejection. Applicants respectfully traverse the Examiner's rejection of the claims 1-5, 7-11 and 17-21 of the instant application over the '764 patent for the following reasons.

"Obviousness-type" double patenting is "judicially created and prohibits an inventor from obtaining a second patent for claims that are not patentably distinct from the claims of the first patent." *In re Lonardo*, 119 F.3d 960, 965 43 USPQ.2d 1262, 1266 (Fed. Cir. 1997). The proper question in an obviousness-type double patenting inquiry is whether the claims at issue would have been obvious to one of ordinary skill in the art over the subject matter of the claims in the first patent. *See, e.g.*, In re Kaplan, 789 F.2d 1574, 1579-80, 229 USPQ 678, 682 (Fed.Cir.1986); In re Longi, 759 F.2d 887, 893, 225 USPQ 645, 648 (Fed.Cir.1985). "In considering the question, the patent disclosure may not be used as prior art." In re Vogel, 57 C.C.P.A. 920, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970). In certain instances the patent disclosure may be used as a dictionary to learn the meaning of terms in a claim. Id. at 441.

Applicants respectfully submit that the claims of the instant application are not an obvious variation of the issued claims of the '764 patent. Applicants incorporate by reference the entirety of their remarks concerning the non-obviousness of the claims of the subject application from Section II above. Applicants respectfully submit that that claims of the present application are patentable distinct from the compounds claimed in the 764 patent. As noted above the Examiner has provided no rationale why one of ordinary skill in the art would obviously arrive at the claimed invention in the absence of the disclosure of the present application under examination. Applicants respectfully submit that the Examiner is using applicants own disclosure as prior art to the instant claims, which is improper.

The Examiner is required to provide the necessary motivation based upon the claims of the '764 patent. The Examiner is using an obvious to try standard by asserting that the claims in the '764 patent makes it obvious to make the claimed invention. More is required. The Examiner needs to point to a motivation or suggestion in the claims of the '764 patent that suggests the compounds of the claimed invention. The Examiner has not done so. The Examiner has failed to provide reasons why one of ordinary skill in the art would concluded that the invention in the instant application is an obvious variation of the invention defined in the claims of the '764 patent. Why would one of ordinary skill in the art select the particular elements claimed in the instant application based upon the claims of the '764 patent? Applicants respectfully submit that those of ordinary skill in the art have a multitude of choices based upon the claims of the '764 patent.

The doctrine of double patenting is intended to prevent a patentee from obtaining a time-wise extension of patent for the same invention or an obvious modification thereof. e.g.,

In re Longi, 759 F.2d 887, 892, 225 USPQ 645, 648 (Fed. Cir. 1985). Applicants respectfully submit that issuance of the claims of the instant application will not result in a time-wise extension of a patent for the same invention. The claims of the instant application are patentable distinct from those of the '764 patent. The compounds claimed in the instant application are distinct from those claimed in the '764 patent claims. Accordingly, applicants are not receiving an extension of the claimed subject matter in the '764 patent by issuance of the claims of the instant application.

Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claim 1-5, 7-11 and 17-21 under obviousness-type-double patenting in view of the claims of the '764 patent. If the Examiner maintains his rejection of the claims of the subject application, applicants respectfully request that the Examiner inform applicants with precision where the motivation or suggestion exists in the art to arrive at the claimed invention in the absence of the specification of the present application.

IV. RESPONSE TO REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

On page 5 of the Action the Examiner rejected claims 1-21 under 35 U.S.C. §112, first paragraph as allegedly not providing enablement for solvates. The Examiner asserts that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with the claims. Applicants respectfully traverse the Examiner's rejection of claims 1-21 as not being enabled for solvates.

The Examiner states that of the hundreds of examples present all fail to produce a solvate. The Examiner also states that applicants must show solvates can be made or limit the claims accordingly. Firstly, applicants are not required to show that solvates exist and for that matter they are not required under the patent law to have even made a compound that falls within the scope of the claimed invention. That is the law. No requirement exists and the Examiner cannot impose such a requirement on applicants.

Applicants respectfully submit that the solvates are well known to those of ordinary skill in the art. It is well known to those of ordinary skill in the art that isolation of compounds in the solid state may result in solvent bound in the solid state (either in crystalline or amorphous forms). It is not uncommon to have solvents such as methylene chloride, ethyl acetate, acetonitrile or methanol forming solvates with organic compounds prepared in these solvents. Preparation of solvates of compounds is well known and

understood by those of ordinary skill in the art. Nothing further is required. The Examiner appears to not believe that solvates of the compounds of the present application exist because applicants have not provided a particular example in the specification of the subject application. There is no requirement that applicants provide evidence supporting the existence or not of such compounds. Where in the patent laws does it require applicants to demonstrate proof the existence of a compound? The Examiner has not provided any valid reason to dispute their existence other than his own non-belief.

On page 5 of the Action the Examiner rejected claims 1-15 and 17-21 under 35 U.S.C. §112, first paragraph as allegedly not providing enablement for $-(CR1R2)_t-$ moiety. The Examiner asserts that that specification does not enable any person skilled in the art to which it pertains or with which it is most nearly connected to make the invention commensurate in scope with the claims. The Examiner states that a double bond would make carbons 5-coordinate and a triple bond would make the carbons with 6-bonds, which the Examiner concludes are impossible. Applicants respectfully submit that this rejection is moot in view of the amendment of substituent R^3 in claim 1 which contained the $-(CR^1R^2)_t-$ moiety. Claim 1 no longer contains the rejected $-(CR^1R^2)_t-$ moiety, accordingly this rejection should be withdrawn.

The Examiner rejected claims 17-19 under 35 U.S.C. §112, first paragraph, asserting that these claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains or which it is most nearly connected to make and/or use the invention. In the interest of expediting the prosecution of the subject application applicants have hereinabove cancelled rejected claims 17-19 without prejudice to their right to pursue patent protection for the cancelled subject matter in a later filed divisional or continuational application. Accordingly, in view of the cancellation of claims 17-19 applicants respectfully submit that the rejection is moot.

In view of the preceding remarks, applicants respectfully request the Examiner reconsider and withdraw his rejection of the claims of the present application under 35 U.S.C. §112, first paragraph.

V. OATH OR DECLARATION

The Examiner states on page 11 of the Action that new oath or declaration in compliance with 37 C.F.R. §1.67(a) identifying the application by application number and filing date is required. The Examiner states that that oath or declaration is defective because the filing date

for the provisional patent application is listed as 6/20/2002 but the PTO records state that the correct date is 6/22/2002. Applicants respectfully submit that a new oath or declaration is not required because the filing dated for the provisional patent application 60/213,136 is 6/20/2002 not 6/22/2002. Applicants have found upon a review of their filing papers for the provisional patent application 60/213,136 that the USPTO incorrectly assigned it the filing date of 6/22/02 and not its date of deposit of 6/20/02. Applicants are concurrently filing at the time of submission of this Amendment a request to the Office of Initial Examination a request for a corrected filing receipt for the provisional application 60/213,136. Once a corrected filing receipt for the provisional patent application is issued applicants will file a request for a correct filing receipt for the subject application 09/883,752, listing the correct filing date for the provisional patent application as 6/20/2002. Applicants respectfully request the Examiner either withdraw this objection based on the preceding remarks or place it in abeyance while they have the filing dates corrected.

CONCLUSION

For the reasons set forth hereinabove, applicant respectfully requests that the Examiner reconsider and withdraw rejections and objection setforth in the December 31, 2002 Office Action and earnestly solicit allowance of the claims pending in the subject application.

Applicants do not believe any fee(s) other than those listed on the fee transmittal sheet are due in connection with this Amendment to the December 31, 2002 Action, however, if any additional fee(s) is due applicants' attorney authorizes payment from deposit account number 16-1445 or credit any overpayment to the aforementioned deposit account.

If the Examiner wishes to comment or discuss any aspect of this application or response, applicants' undersigned attorney invites the Examiner to call him at the telephone number provided below.

Respectfully submitted,

Date: April 29, 2003

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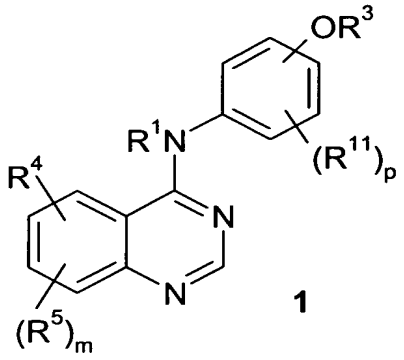
VERSION WITH MARKINGS TO SHOW CHANGES MADE – DO NOT ENTER IN THE CLAIMS

Claims 2, 3 and 17 to 20 have been cancelled. Claim 1 has been amended. Deletions to text in claim 1 are shown below by strikethrough and text insertions are shown in underline.

1. (Amended) A compound of the formula 1



1

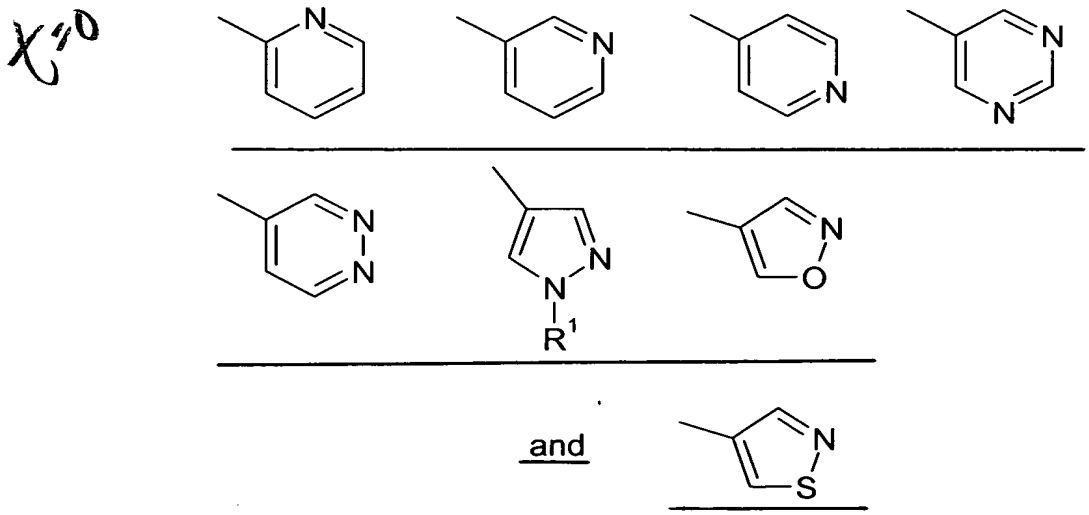
or a pharmaceutically acceptable salt, solvate or prodrug thereof, wherein:

m is an integer from 0 to 3;

p is an integer from 0 to 4;

each R^1 and R^2 is independently selected from H and C_1-C_6 alkyl;

R^3 is selected from



and

wherein the foregoing R^3 groups are optionally substituted by 1 to 3 R^8 groups ~~$-(CR^1R^2)_t$(4 to 10 membered heterocyclic), wherein t is an integer from 0 to 5, said heterocyclic group is optionally fused to a benzene ring or a C_5-C_8 cycloalkyl group, the $-(CR^1R^2)_t$- moiety of the foregoing R^3 group optionally includes a carbon-carbon double or triple bond where t is an integer between 2 and 5, and the foregoing R^3 groups, including any optional fused rings referred to above, are optionally substituted by 1 to 5 R^8 groups~~;

R^4 is $-(CR^{16}R^{17})_m$-C≡C-$(CR^{16}R^{17})_tR^9$, $-(CR^{16}R^{17})_m$-C=C-$(CR^{16}R^{17})_t$-R^9, -$(CR^{16}R^{17})_m$-C≡C-$(CR^{16}R^{17})_kR^{13}$, $-(CR^{16}R^{17})_m$-C=C-$(CR^{16}R^{17})_kR^{13}$, or -$(CR^{16}R^{17})_tR^9$, wherein the attachment point to R^9 is through a carbon atom of the R^9 group, each k is an integer from 1 to 3, each t is an integer from 0 to 5, and each m is an integer from 0 to 3;

each R^5 is independently selected from halo, hydroxy, -NR^1R^2, C_1-C_6 alkyl, trifluoromethyl, C_1-C_6 alkoxy, trifluoromethoxy, -$NR^6C(O)R^1$, -$C(O)NR^6R^7$, -$SO_2NR^6R^7$, -$NR^6C(O)NR^7R^1$, and -$NR^6C(O)OR^7$;

each R^6, R^{6a} and R^7 is independently selected from H, C_1-C_6 alkyl, -$(CR^1R^2)_t$(C_6-C_{10} aryl), and -$(CR^1R^2)_t$(4 to 10 membered heterocyclic), wherein t is an integer from 0 to 5, 1 or 2 ring carbon atoms of the heterocyclic group are optionally substituted with an oxo (=O) moiety, the alkyl, aryl and heterocyclic moieties of the foregoing R^6 and R^7 groups are optionally substituted with 1 to 3 substituents independently selected from halo, cyano, nitro, -NR^1R^2, trifluoromethyl, trifluoromethoxy, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, hydroxy, and C_1-C_6 alkoxy;

or R^6 and R^7, or R^{6a} and R^7, when attached to the same nitrogen atom, can be taken together to form a 4 to 10 membered heterocyclic ring which may include 1 to 3 additional hetero moieties, in addition to the nitrogen to which said R^6, R^{6a}, and R^7 are attached, selected from N, N(R^1), O, and S, provided two O atoms, two S atoms or an O and S atom are not attached directly to each other;

each R^8 is independently selected from oxo (=O), halo, cyano, nitro, trifluoromethoxy, trifluoromethyl, azido, hydroxy, C_1-C_6 alkoxy, C_1-C_{10} alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, -$C(O)R^6$, -$C(O)OR^6$, -$OC(O)R^6$, -$NR^6C(O)R^7$, -$NR^6SO_2NR^7R^1$, -$NR^6C(O)NR^1R^7$, -$NR^6C(O)OR^7$, -$C(O)NR^6R^7$, -NR^6R^7, -NR^6OR^7, -$SO_2NR^6R^7$, -$S(O)_j$(C_1-C_6 alkyl) wherein j is an integer from 0 to 2, -$(CR^1R^2)_t$(C_6-C_{10} aryl), -$(CR^1R^2)_t$(4 to 10 membered heterocyclic), -$(CR^1R^2)_qC(O)(CR^1R^2)_t$($C_6$-$C_{10}$ aryl), -$(CR^1R^2)_qC(O)(CR^1R^2)_t$(4 to 10 membered heterocyclic), -$(CR^1R^2)_tO(CR^1R^2)_q$(C_6-C_{10} aryl), -$(CR^1R^2)_tO(CR^1R^2)_q$(4 to 10 membered heterocyclic), -$(CR^1R^2)_qS(O)_j(CR^1R^2)_t$($C_6$-$C_{10}$ aryl), and -$(CR^1R^2)_qS(O)_j(CR^1R^2)_t$(4 to 10

membered heterocyclic), wherein j is 0, 1 or 2, q and t are each independently an integer from 0 to 5, 1 or 2 ring carbon atoms of the heterocyclic moieties of the foregoing R^8 groups are optionally substituted with an oxo (=O) moiety, and the alkyl, alkenyl, alkynyl, aryl and heterocyclic moieties of the foregoing R^8 groups are optionally substituted with 1 to 3 substituents independently selected from halo, cyano, nitro, trifluoromethyl, trifluoromethoxy, azido, $-OR^6$, $-C(O)R^6$, $-C(O)OR^6$, $-OC(O)R^6$, $-NR^6C(O)R^7$, $-C(O)NR^6R^7$, $-NR^6R^7$, $-NR^6OR^7$, C_1-C_6 alkyl, C_2-C_6 alkenyl, C_2-C_6 alkynyl, $-(CR^1R^2)_t(C_6$-C_{10} aryl), and $-(CR^1R^2)_t$(4 to 10 membered heterocyclic), wherein t is an integer from 0 to 5;

R^9 is a non-aromatic mono-cyclic ring, a fused or bridged bicyclic ring, or a spirocyclic ring, wherein said ring contains from 3 to 12 carbon atoms in which from 0 to 3 carbon atoms are optionally replaced with a hetero moiety independently selected from N, O, $S(O)_j$ wherein j is an integer from 0 to 2, and $-NR^1-$, provided that two O atoms, two $S(O)_j$ moieties, an O atom and a $S(O)_j$ moiety, an N atom and an S atom, or an N atom and an O atom are not attached directly to each other within said ring, and wherein the carbon atoms of said ring are optionally substituted with 1 or 2 R^8 groups;

each R^{11} is independently selected from the substituents provided in the definition of R^8, except R^{11} is not oxo(=O);

R^{12} is R^6, $-OR^6$, $-OC(O)R^6$, $-OC(O)NR^6R^7$, $-OCO_2R^6$, $-S(O)_jR^6$, $-S(O)_jNR^6R^7$, $-NR^6R^7$, $-NR^6C(O)R^7$, $-NR^6SO_2R^7$, $-NR^6C(O)NR^{6a}R^7$, $-NR^6SO_2NR^{6a}R^7$, $-NR^6CO_2R^7$, CN, $-C(O)R^6$, or halo, wherein j is an integer from 0 to 2;

R^{13} is $-NR^1R^{14}$ or $-OR^{14}$;

R^{14} is H, R^{15}, $-C(O)R^{15}$, $-SO_2R^{15}$, $-C(O)NR^{15}R^7$, $-SO_2NR^{15}R^7$, or $-CO_2R^{15}$;

R^{15} is R^{18}, $-(CR^1R^2)_t(C_6$-C_{10} aryl), $-(CR^1R^2)_t$(4 to 10 membered heterocyclic), wherein t is an integer from 0 to 5, 1 or 2 ring carbon atoms of the heterocyclic group are optionally substituted with an oxo (=O) moiety, and the aryl and heterocyclic moieties of the foregoing R^{15} groups are optionally substituted with 1 to 3 R^8 substituents;

each R^{16} and R^{17} is independently selected from H, C_1-C_6 alkyl, and $-CH_2OH$, or R^{16} and R^{17} are taken together as $-CH_2CH_2-$ or $-CH_2CH_2CH_2-$;

R^{18} is C_1-C_6 alkyl wherein each carbon not bound to a N or O atom, or to $S(O)_j$, wherein j is an integer from 0 to 2, is optionally substituted with R^{12};

and wherein any of the above-mentioned substituents comprising a CH_3 (methyl), CH_2 (methylene), or CH (methine) group, which is not attached to a halogeno, SO or SO_2

group or to a N, O or S atom, is optionally subsituted with a group selected from hydroxy, halo, C_1-C_4 alkyl, C_1-C_4 alkoxy and $-NR^1R^2$.